

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' REPLY IN SUPPORT OF MOTION
TO EXCLUDE THE TESTIMONY OF DR. SCOTT GUELCHER, PH.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Dr. Scott Guelcher, Ph.D. [Doc. # 1980 (“Motion”)] and Memorandum of Law in Support [Doc. 1981 (“Mem. in Supp.”)]. Ethicon requests that the Court grant its Motion and reject the arguments raised in Plaintiffs’ Response to the Motion [Doc. # 139 (“Response”)] for the reasons stated below.

I. Ethicon’s Motion Raises Grounds For Excluding Dr. Guelcher That Did Not Exist When The Court Previously Ruled On His Testimony.

The central argument in Plaintiffs’ Response is that Dr. Guelcher should be allowed to testify because this Court previously permitted him to do so in *Huskey*, and nothing has happened in the interim that should change that result. *See* Response at 1 (“The opinions he offers in these Wave 1 cases are the same as the opinions that the Court determined to be relevant and reliable in *Huskey v. Ethicon*.”). As discussed in Ethicon’s Motion, however, much has changed since this Court permitted Dr. Guelcher to testify in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D.W. Va. 2014).

It is wrong to argue that there is nothing new for the Court to consider in Ethicon's Motion. While this Court permitted Dr. Guelcher to testify in *Huskey* based, in part, on its disagreement with Ethicon's position that Prolene is different from other forms of polypropylene, Dr. Guelcher admitted during the *Huskey* trial that Prolene's proprietary antioxidants differentiate it from other forms of polypropylene, making it truly unique. *See* Mem. in Supp. at 3–4. Dr. Guelcher also admitted at the *Huskey* trial that tests have shown that antioxidants have been proven to retard degradation in polypropylene. *See id.* at 4.

Dr. Guelcher's admissions during the *Huskey* trial undermine all of his degradation opinions because it leaves Dr. Guelcher's opinions solely based on scientific literature that simply does not support the conclusion that Prolene oxidizes or degrades *in vivo*.¹ Notably, Plaintiffs do not dispute the fact that the studies on which Dr. Guelcher relies do not address Prolene. Instead, they question why Ethicon would demand scientific literature actually addressing the product at issue in this case. *See* Response at 6 (arguing that "Ethicon's insistence on the need for literature that specifically addresses the degradation or depletion of the antioxidants found in Prolene is completely erroneous."). Tellingly, Plaintiffs do not acknowledge—much less address—Dr. Guelcher's testimony on this issue. Rather, they pretend that Ethicon filed a carbon copy of its motion in *Huskey*, and ask the Court to take the same approach.

Plaintiffs make no mention of the testing Dr. Guelcher conducted with Dr. Russell Dunn, which formed the basis for his opinion that Prolene can oxidize *in vivo*. That testing was found to be scientifically unsound by this Court in *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-

¹ Plaintiffs acknowledge that the scientific literature on which Dr. Guelcher relies does not address Prolene by arguing that "Ethicon's insistence on the need for literature that specifically addresses the degradation or depletion of the antioxidants found in Prolene is completely erroneous." *See* Response at 6.

05851, 2015 WL 2124991, at *22 (S.D.W. Va. May 6, 2015) (excluding opinion of Dr. Dunn because his testing with Dr. Guelcher failed to follow a written protocol or use a sufficient sample size) and Dr. Guelcher was excluded from testifying because of his unreliable testing with Dr. Dunn. *See* Mem. in Supp. at 4–7. Ethicon’s Motion also explained that Dr. Guelcher admittedly undertook this testing in an effort to apply his opinions regarding oxidation of polypropylene to Prolene specifically. *See id.* Although that test cuts to the core of his opinions, Dr. Guelcher refused to rely on it in this litigation and has gone to great effort to distance himself from it. *Id.* at 7–8 n.10.

Plaintiffs side-step these reliability problems, instead arguing that the Court should disregard this new testing because Dr. Guelcher refuses to rely on it in this litigation. *See* Response at 4–5. It is, of course, more convenient for Plaintiffs if Dr. Guelcher’s failed attempt to support the conclusions he offers in this case were forgotten and buried. The facts are that, since *Huskey*, Dr. Guelcher conducted testing to prove his opinions about Prolene, published an abstract and delivered presentations based on that testing, and this Court found that testing to be unreliable and excluded him from testifying about it in pelvic mesh litigation. *See* Mem. in Supp. at 5–6.

Plaintiffs’ assertion that there is nothing new for this Court to consider is belied by Dr. Guelcher’s own testimony and testing. The Court should consider Dr. Guelcher’s testimony in the context of these real reliability issues that have arisen since *Huskey* and exclude Dr. Guelcher’s opinions from this case.

II. Dr. Guelcher’s Opinions Regarding Prolene’s Antioxidant Package Are Pure Speculation.

Plaintiffs claim that there is no scientific basis for the Court to exclude Dr. Guelcher’s opinions in this case because he says it was “not possible” for Prolene’s antioxidant package to

account for reactive oxygen species or the foreign body response, as they were not discovered until 1990. *See* Response at 6. In other words, the intention of the designers is the sole determining factor of how a product works. This opinion is baseless, illogical speculation. It is not impossible that designers in the 1960s could unknowingly develop a product that accounts for an undiscovered body response.

Dr. Guelcher doesn't know whether Prolene's proprietary antioxidant can withstand the body's foreign body response. What the designers of Prolene knew or didn't know is not the litmus test for determining how it actually works. Dr. Guelcher admits that Prolene is a unique form of polypropylene, (Mem in Supp. at 3–4) and as Ethicon's Motion explains, the scientific literature on which Dr. Guelcher relies does not establish that Prolene oxidizes *in vivo* (*id.* at 9–15).² Dr. Guelcher has never conducted any test that shows Prolene oxidizes *in vivo*, and he now intentionally backs away and distances himself from his own testing intended to determine whether Prolene oxidizes under certain *in vitro* conditions. *Id.* at 6–8.

There is no scientific foundation for Dr. Guelcher's opinions that Prolene's antioxidant package cannot withstand the foreign body reaction. Rather, Dr. Guelcher simply assumes it cannot because Prolene was formulated in the 1960s. *See* Reply Ex. FF, *Huskey* 8/25/14 Trial Tr. 115:18–23. But both Dr. Guelcher and Plaintiffs ignore the fact that Prolene has been used safely and effectively in the human body since that time.

The Court should reject Plaintiffs' unsubstantiated arguments, and preclude Dr. Guelcher from speculating before the jury.

² To the extent Dr. Guelcher relies on internal Ethicon documents, those documents do not support his opinions for the reasons discussed in Ethicon's Motion. *See* Mem. in Supp. at 14–15.

III. Dr. Guelcher's Refusal to Rely on His Own Testing Shows That His Opinions Are Unreliable.

Under *Daubert* and its progeny, a key inquiry in determining the reliability of an expert's opinion is "whether it can be (and has been) tested." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993); *see also Hodges v. Federal-Mogul Corp.*, No. 7:12-cv-00362, 2014 WL 901214 at *9 (W.D. Va. Mar. 7, 2014) ("[T]he absence of physical testing or modeling in an expert methodology can impact the reliability of that expert's opinion. The Fourth Circuit has repeatedly upheld district court decisions excluding expert opinions as unreliable due to a lack of testing.").

Dr. Guelcher not only recognized that his opinion was subject to testing, but he actually conducted the testing and sought to rely on it both in and out of court. *See* Mem. in Supp. at 4–7. That testing goes to the heart of the opinions he offers in this case. But now he is unable to rely on that testing to support his opinion that Prolene degrades *in vivo*. As discussed in Ethicon's Motion, Dr. Guelcher's refusal to rely on his own testing to support his opinions, coupled with his obfuscation regarding the testing, proves the lack of reliability in his opinions. The Court should exclude his opinions on that basis alone.

a. Dr. Guelcher's Refusal to Rely on His Test is Relevant.

Plaintiffs assert that Ethicon's arguments regarding the testing Dr. Guelcher conducted with Dr. Dunn on TVT are irrelevant because he is not relying on it in this litigation, and it "was never central to his opinions in these cases." Response at 4–5. But Plaintiffs' argument ignores the fact that Dr. Guelcher's testimony established the centrality of this testing to his opinions. Indeed, in Dr. Guelcher's own words:

[T]he motivation for the tests was based on Ethicon's statements during trial that we had not tested it and . . . we **could not say definitively that Prolene polypropylene oxidizes,** and that was the motivation for the test. So this was what was said in *Huskey* trial, we

decided to do the test to answer that specific question, can Prolene polypropylene oxidize.

Motion Ex. C, Guelcher 12/18/14 Dep. Tr. 108:3–12 (emphasis added). *See also* Mem. in Supp. at 5.

He also testified that he believed that this testing “show[ed] Prolene polypropylene used to manufacture the TVT device can oxidize and degrade under oxidative conditions similar to those experienced in the human body after implantation.” Motion Ex. C, Guelcher 12/18/14 Dep. Tr. 123:25–124:8. But now Dr. Guelcher admits that he cannot answer the “specific question” of “can Prolene polypropylene oxidize.” *Id.* at 108:3–12. Plaintiffs’ assertion that this testing was “never central to his opinions in these cases” is simply disingenuous.

In summary, Plaintiffs ask the Court to overlook the events of the past two years since *Huskey*, including that:

- Dr. Guelcher admitted at trial that Prolene is different than other forms of polypropylene (*see* Mem. in Supp. at 3–4);
- Dr. Guelcher conducted testing in an effort to prove that Prolene oxidizes just like other forms of polypropylene (*see id.* at 4–5);
- Dr. Guelcher relied on that testing both in and out of litigation (*see id.* at 5–8);
- Dr. Guelcher’s testing was found by this Court to be unreliable (*see id.* at 2); and
- Dr. Guelcher refused to rely on his testing in this case because it “was never central to his opinions in these cases.” (Response at 4).

The Court should reject Plaintiffs’ invitation to turn a blind eye to these facts, and preclude Dr. Guelcher from testifying in this case.

b. Plaintiffs’ attempts to bolster Dr. Guelcher’s unreliable testing are without merit.

Plaintiffs argue that Dr. Guelcher’s testing is irrelevant in this case, but, in the next breath, Plaintiffs curiously attempt to defend the reliability of his testing by claiming that the

criticisms offered by Ethicon's experts—Dr. Shelby Thames and Dr. Steven MacLean—are unreliable. *See* Response at 5. Without explanation, Plaintiffs ask the Court to reject Dr. Thames and MacLean's criticisms because they are "nonspecific and uninformed." *Id.*

Drs. Thames and MacLean offer reliable and methodologically sound analyses explaining the lack of reliability in Dr. Guelcher's testing. Dr. MacLean's expert report described a key methodological flaw in Dr. Guelcher's test—Dr. Guelcher's test never established that his methods were scientifically valid for analyzing polypropylene or Prolene. *See* Motion at Ex. P, MacLean Report at 34–35. The Anderson study on which Dr. Guelcher's testing was purportedly based shows that the oxidative medium used in Dr. Guelcher's test was validated to mimic *in vivo* conditions for poly(etherurethane), and not for other polymers. *See* Reply Ex. GG, Q.H. Zhao, et al., *Human Plasma Macroglobulin Promotes in Vitro Oxidative Stress Cracking of Pellethane 2363A: In vivo and in vitro correlations*, 27 J. Biomed. Materials Res. 379–89 (1993). Dr. MacLean also explained that the "pitting and flaking" shown in Dr. Guelcher's SEM image was inconsistent with the morphological features that allegedly represent oxidation that are seen in explanted polypropylene samples. *See* Motion at Ex. P, MacLean Report at 34–35.

Additionally, Dr. Thames analyzed the actual data from Dr. Guelcher's test and recorded detailed findings about Dr. Guelcher's analysis in his expert report submitted in this case. *See* Motion at Ex. O, Thames Report at 69–71. Dr. Thames examined the FTIR data from the test and found no evidence of oxidation. *Id.* at 69 (finding no carbonyl peaks indicative of oxidation in the samples exposed to the oxidative medium). Dr. Thames also explained that the SEM analysis was not conducted in accordance with proper scientific methodology. *Id.* at 70 (explaining that there were insufficient efforts to remove the oxidative medium from the samples, and that the control samples were not subjected to the same analysis as the samples

being tested). Dr. Thames found that the data from the test's x-ray photoelectron spectroscopy analysis confirmed that the test was flawed. *Id.* at 70–71 (explaining although “all samples of TVT should exhibit carbonyl configurations (C=O)” because two of Prolene's additives contain C=O configurations, the XPS from Dr. Guelcher's test showed only 4 samples contained C=O configurations).

The Court should reject Plaintiffs' transparent attempt to distract the Court from the obvious unreliability and scientific inadequacy of Dr. Guelcher's testing and methodology.

IV. Dr. Guelcher's In-Court Opinions Regarding Complications Are Inconsistent With His Publications.

Although Plaintiffs ask the Court to permit Dr. Guelcher to opine about potential complications (Response at 8–9), they make no effort to show that he is qualified to do that (*see* Mem. in Supp. at 16–17). Plaintiffs also fail to address Dr. Guelcher's admission that he cannot correlate degradation with any specific complication because he does not have the data necessary to reach those conclusions. *See* Response at 8–9; *see also* Mem. in Supp. at 17.

Furthermore, Ethicon's Motion explains that Dr. Guelcher's own publications do not support his opinions regarding the complications allegedly caused by degradation. *See* Mem. in Supp. at 17–18 (discussing a study Dr. Guelcher co-authored with Dr. V. Iakovlev—*Degradation of Polypropylene In Vivo: A Microscopic Analysis of Meshes Explanted From Patients*, J. Biomed. Materials Res. Part B 10–11 (2015) (“*Degradation of Polypropylene*”). Plaintiffs attempt to downplay the significance of Dr. Guelcher's paper by claiming that it is merely a “teaching publication” that was “not focused on understanding injuries like chronic mesh-pain.” Response at 8.

No matter how Plaintiffs wish to characterize the paper, it expressly states that the “exact mechanisms of these late complications are yet to be understood” and the role of degradation

“need[s] to be studied more extensively for [its] role[] in the development of these complications.” Motion at Ex. R, *Degradation of Polypropylene*, at 10–11. But notwithstanding the unambiguous acknowledgement in Dr. Guelcher’s paper that the causal mechanisms for complications are not known, he seeks to tell a jury—to a reasonable degree of scientific certainty—that the degradation of Prolene mesh used in TVT cause complications in women.

The Court should not permit Dr. Guelcher’s to offer opinions to the jury that vastly exceed the conclusions he presents to the scientific community in his own peer-reviewed publications. *See Kumho Tire, et al., v. Carmichael*, 526 U.S. 137, 152 (1999) (explaining that an expert must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”).

V. The Mary Study Does Not Reliably Support Dr. Guelcher’s Opinions about Prolene Degradation.

Plaintiff cites a 1998 study by Celine Mary and others as peer-reviewed literature supporting Dr. Guelcher’s opinions that Prolene can degrade. Response at 2 & Ex. C. However, as explained in Ethicon’s Memorandum of Law in Support of Motion to Exclude the Opinions and Testimony of Dr. Jimmy W. Mays [ECF No. 2047], the Mary study used unreliable methods and cannot be reliably used to support any opinions that Prolene is susceptible to degradation. *Id.* at 8–9. Accordingly, to the extent Dr. Guelcher relied on the Mary study to support his opinions, this reliance does not make his opinions reliable.

VI. Dr. Guelcher’s Opinions and Testimony Regarding Prolene is Unfairly Prejudicial Unless Evidence of FDA Actions Regarding Prolene is Admitted.

Plaintiffs appear to misunderstand Ethicon’s argument regarding evidence about the degradation of Prolene sutures. Plaintiffs claim that the FDA’s actions with respect to Prolene sutures “has nothing to do” with the alleged degradation about which Dr. Guelcher seeks to testify, and that “[t]his Court has previously allowed Dr. Guelcher to rely on these internal

Ethicon documents without needing to admit evidence relating to the FDA or its processes.” Response at 7–8.

As an initial matter, Plaintiffs ignore the fact that this Court has never addressed this issue, as Ethicon raised this argument for the first time in its motion to exclude Dr. Guelcher’s testimony in *Mullins*, which has not yet been ruled on by this Court. *See* Def. Mem. Law in Supp. Mot. Exclude Test. of Dr. Scott Guelcher, Ph.D., *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952 [Doc. # 113]. More importantly, Plaintiffs fail to understand that Ethicon’s argument is a simple analysis pursuant to Federal Rule of Evidence 403.

Dr. Guelcher seeks to testify about internal Ethicon studies that deal exclusively with Prolene sutures. *See* Mem. in Supp. at 14–16. Unless the Court excludes Dr. Guelcher’s testimony regarding these suture studies, he will be allowed to opine before the jury that Prolene sutures can degrade *in vivo*. The jury will likely infer from Dr. Guelcher’s testimony that this degradation is somehow clinically significant, despite the absence of any evidence to support that inference.

The risk of unfair prejudice to Ethicon can only be remedied by precluding Dr. Guelcher from testifying about or relying on studies regarding suture degradation, or allowing Ethicon to introduce evidence that the FDA determined that Prolene sutures were safe and effective, and made an express finding that any *in vivo* degradation was not clinically significant. *See* Reply Ex. HH, FDA Reclassification of Prolene*, Polypropylene Nonabsorbable Suture (1990) at p. 7. Unless Ethicon is given a chance to rebut any erroneous inference with evidence of the FDA’s regulatory actions—actions that would preempt any state law claims that Prolene sutures were defectively designed—Ethicon will be unfairly prejudiced and the jury will be confused or

misled into concluding that Prolene mesh is defective based on the erroneous assumption that Prolene sutures cause clinically significant complications *in vivo*.

VII. Conclusion

For all of these reasons, as well as those set forth in Ethicon's Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Testimony of Dr. Scott Guelcher.

Respectfully submitted,

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1800
dthomas@tcspllc.com

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

COUNSEL FOR DEFENDANTS ETHICON, INC.
AND JOHNSON & JOHNSON

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

COUNSEL FOR DEFENDANTS ETHICON, INC.
AND JOHNSON & JOHNSON